

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Richard F. Wenstrom Jr. et al. Confirmation No.: 2466

Appln. No. : 10/708,467 Art Unit : 3733

Filed : March 5, 2004 Examiner : Hoffman, Mary C.

Title : TUNNEL NOTCHER AND GUIDEWIRE DELIVERY DEVICE

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August 24, 2010

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August 24, 2010

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Commissioner for Patents
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APPEAL BRIEF

Dear Sir:

I. REAL PARTY IN INTEREST

By virtue of an assignment recorded at reel/frame 015482/0675 this application is assigned to DePuy Mitek, Inc. which is a subsidiary of Johnson & Johnson, a New Jersey corporation.

II. RELATED APPEALS AND INTERFERENCES

None

III. STATUS OF THE CLAIMS

Claims 1-3, 5-18, 34, 35 and 37 stand rejected. Claims 4, 19-33 and 36 are cancelled.

IV. STATUS OF THE AMENDMENTS

An amendment was filed April 21, 2010 after issuance of the Final Office Action. In an Advisory Action mailed May 4, 2010 the Examiner indicated that the amendment would not be entered. Applicants subsequently petitioned for entry of the amendment. The Examiner contended in the Advisory Action that the amendment eliminating a claim element would broaden the claims thus requiring a new search. Applicants contend that the claim element was missing when the Examiner performed the initial search, was subsequently added and is now sought to be removed; the claims lacking the element being once searched require no new

search. No decision has been entered on the Petition as of the date of this brief. Accordingly, Applicants submit two versions of the claims in Appendix A, one version assuming the Petition is granted, and another assuming the Petition is denied.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 1 defines a tunnel notcher and guidewire delivery device 10. It comprises an elongate member 12 with proximal and distal ends 12a and 12b and an inner lumen 12c extending therebetween, the inner lumen being adapted to receive a guidewire 16. A cutting element 18 having a distal bone cutting edge 18a disposed proximal to the distal portion of the elongate member and is spaced away from the elongate member. It is adapted to remove bone 52 within an opening of a bone tunnel 56, the cutting element being the only cutting element disposed on the elongate member and being substantially wedge-shaped and extending radially outward from the elongate member. (See FIGS. 1, 2A and 4B and Specification paragraphs [0008], [0023], [0025], [0028] and [0029])

Claim 34 defines a tunnel notcher and guidewire delivery device 10. It comprises an elongate member 12 with proximal and distal ends 12a and 12 b and an inner lumen 12c extending therebetween, the inner lumen being adapted to receive a guidewire. A single cutting element 18 is disposed proximal to the distal end of the elongate member and adapted to remove bone 52 within an opening of a bone tunnel 56. The cutting element is the only cutting element disposed on the elongate member, is substantially wedge-shaped, extends radially outward from the elongate member and has a bone cutting edge 18a that has a substantially arcuate shape spaced apart from and circumferentially oriented with respect to the elongate

member. (See FIGS. 1, 2A and 4B and Specification paragraphs [0008], [0023], [0025], [0028] and [0029])

Claim 35 defines a tunnel notcher and guidewire delivery device 10. It comprises an elongate member 12 with proximal and distal ends 12a and 12b and an inner lumen 12c extending therebetween, the inner lumen being adapted to receive a guidewire. A single cutting element 18 is disposed proximal to the distal end of the elongate member and is adapted to remove bone 52 within an opening of a bone tunnel 56. The cutting element is the only cutting element disposed on the elongate member, and is substantially wedge-shaped such that a width of the cutting element increases in a proximal to distal direction. (See FIGS. 1, 2A and 4B and Specification paragraphs [0008], [0023], [0025], [0028] and [0029])

VI. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

A. The rejection under 35 U.S.C. §112 of claims 1 to 3 and 5 to 18, first paragraph.

B. The rejection under 35 U.S.C. §102(b) of claims 1 to 3, 5, 9 to 15, 34, 35 and 37 over U.S. Patent No. 5,807,276 to Russin et al.

VII. ARGUMENT

A. The rejection under 35 U.S.C. §112 of claims 1 to 3 and 5 to 18, first paragraph.

Applicants added the element which forms the basis of this rejection during prosecution. When attempting to remove the element to narrow the issues for appeal the Examiner refused on the grounds that it would broaden the claims thus

requiring a new search. Applicants question the validity of this line of argument when the Examiner previously searched the claims lacking such element. Was the initial search inadequate? Applicants have petitioned for entry of the amendment and as of the date of this brief such petition has not been acted upon. If the petition is granted this grounds for rejection becomes moot.

If the petition is not granted and the limitation stays Applicants submit that the rejection is in error. The Examiner opines that the specification lacks sufficient description to support the limitation of the “cutting edge being ... not normal to the elongate member.” FIG. 2A and the paragraph [0029] shows the arcuate cutting edge 18a being spaced apart from and not normal to the longitudinal axis L. An arcuate element is not normal to a line.

B. The rejection under 35 U.S.C. §102(b) of claims 1 to 3, 5, 9 to 15, 34, 35 and 37 over U.S. Patent No. 5,807,276 to Russin et al.

The Examiner has improperly rejected claims 1 to 3, 5 and 9 to 15 under 35 U.S.C. §102(b) over Russin et al. Russin et al. neither teach nor suggest the claimed invention.

Applicants have invented a tunnel notcher and guidewire delivery device for creating a notch and positioning a guidewire within a bone tunnel. An Anterior Cruciate Ligament (ACL) in a knee may be reconstructed by replacing the ruptured ACL with a graft ligament. For instance bone tunnels can be formed in the top end of the tibia and the bottom end of the femur, and one end of the graft ligament positioned in the femoral bone tunnel and the other end of the graft ligament is positioned in the tibial bone tunnel. In one common method for anchoring an end of the graft ligament in a bone tunnel the end of the graft is attached to an

anchoring member, such as a bone plug, that is inserted into a bone tunnel and secured therein with an interference screw between the plug and the bone. Such a procedure typically requires a recess to be formed in the bone adjacent to the bone tunnel to allow the bone screw to be inserted alongside the bone plug. The recess serves as a "starter hole" for the bone screw so that the screw can engage bone in a generally proper direction with respect to the bone tunnel. As the bone screw is threaded into the bone, the resulting interference fit between the bone plug and the bone screw secures the graft ligament in place in the bone tunnel.

The present invention provides an improved tool for providing the recess and for implanting a guidewire for guiding implantation of the screw. This tool comprises an elongated member with an inner lumen for receipt of the guidewire. A cutting element having a distal bone cutting edge is disposed proximal to a distal portion of the elongate member, and is spaced away from the elongate member. The cutting element is the only cutting element disposed on the elongate member, is substantially wedge-shaped and extends radially outward from the elongate member. It is adapted to remove bone within the opening of a bone tunnel, i.e. for cutting the recess into the bone as the elongated member is pushed into the bone hole.

Russin et al. teach a biopsy device having a tubular body and a sliding scalpel blade which extends from and is oriented normal to the body. The present invention differs from the device of Russin et al. It defines a bone cutting edge and defines that the bone cutting edge is spaced away from the elongated member and adapted for removing bone. Russin does not disclose a bone cutting edge, especially one adapted for removing bone. Russin et al. disclose only a scalpel suitable for cutting soft tissue. Moreover, the scalpel blade of Russin et al. touches

the body rather than being spaced away. Failing to teach each and every limitation of the presently claimed invention Russin et al. fail to anticipate.

If the Petition is not granted claim 1 further defines that the cutting element is not normal to the elongate member, whereas the scalpel of Russin et al. is normal to the elongate member.

Claim 5 defines a distal facing surface of the cutting element which forms an acute angle with respect to a longitudinal axis of the elongate member. The distal facing surface in Russin et al. would be the scalpel blade which sits at an obtuse angle rather than an acute angle.

Claim 6 further defines the distal facing surface as being concave. The Russin et al. reference lacks such a showing.

Claim 7 defines the angle between the distal facing surface of the cutting element to be less than 90 degrees with respect to the longitudinal axis of the elongate member wherein the scalpel blade of Russin et al. is more than 90 degrees.

Claim 8 further defines the angle to be between 20 and 70 degrees wherein it clearly exceeds 90 degrees in Russin et al.

Claim 9 defines the cutting element to have a base portion coupled to the elongate member and a cutting edge positioned a distance apart from the elongate member. The scalpel of Russin et al. touches the elongate member rather than being positioned a distance apart from it.

Claim 10 has the cutting edge being positioned distal to the base portion wherein in Russin et al. the scalpel edge extends proximally backwards over the base portion.

Claim 11 defines the cutting edge as being positioned a distance apart from the elongate member and having a length less than a diameter of the elongate member. The cutting edge of Russin et al. clearly is longer than the diameter of the elongate member.

Claim 12 defines the cutting element being adapted to create a notch in bone having a substantially semi-circular shape. The Russin et al. reference lacks a cutting element adapted to create a notch in bone, much less one adapted to create one semi-circular in shape.

Claim 14 defines a handle on the elongate member. Russin et al.'s elongate member lacks a handle.

Claim 15 further defines the handle as extending transversely. Russin et al. lack a handle and lack one transverse to the elongate member.

Claim 16 defines a locking mechanism adapted to lock the guidewire in a fixed position with respect to the elongate member. The Russin et al. reference lacks such disclosure.

Claim 17 positions the locking mechanism on a handle on a proximal portion of the elongate body. The Russin et al. reference lacks both the locking mechanism and the handle bearing such mechanism.

Claim 18 further defines the locking mechanism being a threaded member disposed within a threaded bore in the handle. Russin et al. lack such disclosure.

Claim 34 defines the cutting edge as having an arcuate shape spaced apart from and circumferentially oriented with respect to the elongate body. Russin et al.'s scalpel blade is not arcuate, spaced apart from the elongate body or circumferentially oriented with respect to the elongate body.

Claim 35 provides that the bone cutting element is substantially wedge-shaped such that a width of the cutting element increases in a proximal to distal direction. The blade of Russin et al. does not increase in width in that direction.

Applicants submit that the Examiner has failed to establish a prima facie case of obviousness and request withdrawal of the rejections and passage of the application onto issue.

Respectfully submitted,

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CLAIMS APPENDIX

[ASSUMING GRANT OF THE PETITION TO ENTER THE AFTER FINAL
AMENDMENT]

1. A tunnel notcher and guidewire delivery device, comprising:
an elongate member with proximal and distal ends and an inner lumen
extending therebetween, the inner lumen being adapted to receive a guidewire; and
a cutting element having a distal bone cutting edge disposed proximal to a
distal portion of the elongate member, and being spaced away from the elongate
member, the cutting element being adapted to remove bone within an opening of a
bone tunnel, the cutting element being the only cutting element disposed on the
elongate member and being substantially wedge-shaped and extending radially
outward from the elongate member.
2. The device of claim 1, wherein a distal portion of the distal end of the
elongate member is substantially tapered.
3. The device of claim 2, wherein the cutting element is disposed
proximal to the substantially tapered distal portion of the elongate member.
5. The device of claim 1, wherein the cutting element includes a distal-
facing surface that is disposed at an acute angle with respect to a longitudinal axis
of the elongate member.
6. The device of claim 5, wherein the distal-facing surface is
substantially concave.

7. The device of claim 6, wherein the angle between the distal facing surface of the cutting element and the longitudinal axis of the elongate member is less than 90°.

8. The device of claim 7, wherein the angle is in the range of about 20° to 70°.

9. The device of claim 1, wherein the cutting element includes a base portion coupled to the elongate member and a cutting edge positioned a distance apart from the elongate member.

10. The device of claim 9, wherein the cutting edge is positioned distal to the base portion.

11. The device of claim 9, wherein the cutting edge that is positioned a distance apart from the elongate member has a length that is less than a diameter of the elongate member.

12. The device of claim 1, wherein the cutting element is adapted to create a notch in bone having a substantially semi-circular shape.

13. The device of claim 1, further comprising a plurality of indicia formed on a distal portion of the elongate member and adapted to indicate a depth of the elongate member within a bone tunnel.

14. The device of claim 1, further comprising a handle disposed on a proximal portion of the elongate member.

15. The device of claim 14, wherein the handle extends in a direction transverse to a longitudinal axis of the elongate member.

16. The device of claim 1, further comprising a locking mechanism adapted to lock the guidewire in a fixed position with respect to the elongate member.

17. The device claim 16, wherein the locking mechanism is formed on a handle mated to the proximal end of the elongate member.

18. The device of claim 17, wherein the locking mechanism comprises a threaded member disposed within a threaded bore formed in the handle, the threaded bore being in communication with the inner lumen of the elongate member.

34. A tunnel notcher and guidewire delivery device, comprising:
an elongate member with proximal and distal ends and an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire; and
a single cutting element disposed proximal to the distal end of the elongate member and adapted to remove bone within an opening of a bone tunnel, the cutting element being the only cutting element disposed on the elongate member and being substantially wedge-shaped and extending radially outward from the elongate member and having a bone cutting edge that has a substantially arcuate shape spaced apart from and circumferentially oriented with respect to the elongate member.

35. A tunnel notcher and guidewire delivery device, comprising:
an elongate member with proximal and distal ends and an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire; and
a single cutting element disposed proximal to the distal end of the elongate member and adapted to remove bone within an opening of a bone tunnel, the cutting element being the only cutting element disposed on the elongate member

and being substantially wedge-shaped such that a width of the cutting element increases in a proximal to distal direction.

37. The device of claim 1 wherein the distal portion of the elongate member has a length greater than a length of the cutting element.

CLAIMS APPENDIX

[ASSUMING THE PETITION REQUESTING ENTRY OF THE AFTER FINAL
AMENDMENT IS NOT GRANTED]

1. A tunnel notcher and guidewire delivery device, comprising:
an elongate member with proximal and distal ends and an inner lumen
extending therebetween, the inner lumen being adapted to receive a guidewire; and
a cutting element having a distal bone cutting edge disposed proximal to a
distal portion of the elongate member, and being spaced away from and not normal
to the elongate member, the cutting element being adapted to remove bone within
an opening of a bone tunnel, the cutting element being the only cutting element
disposed on the elongate member and being substantially wedge-shaped and
extending radially outward from the elongate member.
2. The device of claim 1, wherein a distal portion of the distal end of the
elongate member is substantially tapered.
3. The device of claim 2, wherein the cutting element is disposed
proximal to the substantially tapered distal portion of the elongate member.
5. The device of claim 1, wherein the cutting element includes a distal-
facing surface that is disposed at an acute angle with respect to a longitudinal axis
of the elongate member.
6. The device of claim 5, wherein the distal-facing surface is
substantially concave.
7. The device of claim 6, wherein the angle between the distal facing
surface of the cutting element and the longitudinal axis of the elongate member is
less than 90°.

8. The device of claim 7, wherein the angle is in the range of about 20° to 70°.

9. The device of claim 1, wherein the cutting element includes a base portion coupled to the elongate member and a cutting edge positioned a distance apart from the elongate member.

10. The device of claim 9, wherein the cutting edge is positioned distal to the base portion.

11. The device of claim 9, wherein the cutting edge that is positioned a distance apart from the elongate member has a length that is less than a diameter of the elongate member.

12. The device of claim 1, wherein the cutting element is adapted to create a notch in bone having a substantially semi-circular shape.

13. The device of claim 1, further comprising a plurality of indicia formed on a distal portion of the elongate member and adapted to indicate a depth of the elongate member within a bone tunnel.

14. The device of claim 1, further comprising a handle disposed on a proximal portion of the elongate member.

15. The device of claim 14, wherein the handle extends in a direction transverse to a longitudinal axis of the elongate member.

16. The device of claim 1, further comprising a locking mechanism adapted to lock the guidewire in a fixed position with respect to the elongate member.

17. The device claim 16, wherein the locking mechanism is formed on a handle mated to the proximal end of the elongate member.

18. The device of claim 17, wherein the locking mechanism comprises a threaded member disposed within a threaded bore formed in the handle, the threaded bore being in communication with the inner lumen of the elongate member.

34. A tunnel notcher and guidewire delivery device, comprising:
an elongate member with proximal and distal ends and an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire; and
a single cutting element disposed proximal to the distal end of the elongate member and adapted to remove bone within an opening of a bone tunnel, the cutting element being the only cutting element disposed on the elongate member and being substantially wedge-shaped and extending radially outward from the elongate member and having a bone cutting edge that has a substantially arcuate shape spaced apart from and circumferentially oriented with respect to the elongate member.

35. A tunnel notcher and guidewire delivery device, comprising:
an elongate member with proximal and distal ends and an inner lumen extending therebetween, the inner lumen being adapted to receive a guidewire; and
a single cutting element disposed proximal to the distal end of the elongate member and adapted to remove bone within an opening of a bone tunnel, the cutting element being the only cutting element disposed on the elongate member and being substantially wedge-shaped such that a width of the cutting element increases in a proximal to distal direction.

37. The device of claim 1 wherein the distal portion of the elongate member has a length greater than a length of the cutting element.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None